K121545

JUN - 8 2012

CIVCO MEDICAL SOLUTIONS

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Section 5.0 – 510(k) Summary

CIVCO MR & Radiological Patient Positioning Devices

A. General Information

Submitter's Name:	MEDTEC, Inc. d/b/a CIVCO Medical Solutions
Address:	1401 8th Street SE, Orange City, Iowa 51041
Telephone No.:	319-248-6628
Fax No.:	877-218-0324
Contact Person:	Amanda Stahle, Regulatory Affairs Specialist
Date Summary Prepared:	March 16, 2012
Trade Name:	Bellyboard, SBRT Accessories
Common Name:	MR & Radiological Patient Positioning Devices
Classification Names:	System, Nuclear Magnetic Resonance Imaging (21 CFR 892.1000, Product Code LNH)
	Accelerator, Linear, Medical (21 CFR 892.5050, Product Code IYE)

B. Predicate Devices

MEDTEC, Inc., doing business as CIVCO Medical Solutions, claims the proposed devices to be substantially equivalent to the following devices devices previously cleared by the FDA in the following 510(k)s:

- **Bellyboard**
  - K060737 – Sinmed Immobilization Systems (Head and Shoulder, Lung and Thorax, Pelvis and Lower Extremities, and Posicast) and Sinmed Repovac Cushions
- **SBRT Accessories**
  - K973842 – MEDTEC, Inc. Carbon Fiber Conformal Couch Top

The predicate devices have been used for many years in radiological and other medical procedures. The purpose of this 510(k) is to have these products cleared for use in the MR environment.

The predicate devices have the same intended use with the exception of use in the MR environment. The design and materials have been changed where necessary to use these products in the MR environment. CIVCO has conducted testing to demonstrate that the changes in design and materials do not affect the safety and effectiveness of the device.

C. Device Description

The MR & Radiological Patient Positioning devices are used to aid in patient positioning and immobilization during radiotherapy procedures. The following models of the Patient Positioning Devices are included in this submission:

- **Bellyboard**
  126000 Bellyboard, which includes the following:
  301101 Bellyboard Cushion
- **SBRT Accessories**
  MTSBRT011 SBRT Patient Transfer System, which includes the following:
  MTSBRT012 Gurney Plate Assembly
  MTSBRT032 Transfer System Trans Slot
  MTSBRT033 Transfer System Longitudinal Slot
  MTSBRT014 Ski Assembly
  20-CFHN-017 Type-S Strap

Devices are sold non-sterile and may be reused for multiple patient or single patient use if set-up for a single patient. The proposed devices are non-implanted devices that are large in size and manufactured of non-magnetic and plastic materials.

D. Intended Use/Indications for Use

CIVCO Patient Positioning Devices are used to aid in the support and positioning of patients during MR, radiological, and other procedures.

E. Technological Characteristics

Technological characteristics which have changed between the proposed and predicate devices include changes in the design and materials which were tested for use in a MR environment to ensure these differences do not affect the safety and effectiveness of the device. These changes include the use of fiberglass instead of carbon fiber, and the addition of a third hole to secure the device in the MR environment, preventing non-MR compatible devices from being used in the MR environment.

F. Non-Clinical Testing

MR compatibility test methodology generally followed ASTM Standards F2182-9, F2119-07, F2052-06 and F2213-06, but modifications were made to accommodate the large size of the proposed devices and to accommodate their external use (not implanted). The devices passed the acceptance criteria for RF heating, magnetic

induced torque, and magnetically induced displacement force and demonstrate that the device is safe for use in the MR environment. Image artifact was observed in a specific area of the SBRT Patient Transfer System, but the device has been labeled MR conditional to account for this artifact. Biocompatibility testing was also completed for patient contacting materials.

G. Conclusion

This premarket submission for the CIVCO MR & Radiological Patient Positioning Devices has demonstrated Substantial Equivalence as defined and understood in the Federal Food, Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health. Based on comparison against current product offering and predicate devices, CIVCO MR & Radiological Patient Positioning Devices are safe and effective for their intended and indicated use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

MEDTEC Inc. dba CIVCO Medical Solutions
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

JUL 9 2012

Re: K121545
Trade/Device Name: MR & Radiological Patient Positioning Devices
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH and IYE
Dated: May 24, 2012
Received: May 25, 2012

Dear Mr. Job:

This letter corrects our substantially equivalent letter of June 8, 2012.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): TBD K121545

Device Name: MR & Radiological Patient Positioning Devices

Indications for Use: CIVCO Patient Positioning Devices are used to aid in the support and positioning of patients during MR, radiological, and other procedures.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K121545